K090569
p1 of 2

4.0 510(k) Summary

3M™ Attest™ Rapid Read-Out Biological Indicator (#1292)

1. Sponsor:

3M Infection Prevention Division
3M Center, Bldg 275-5W-06
St. Paul, MN 55144

APR 2 9 2009

Contact Person:
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Infection Prevention Division
3M Center, Bldg 275-5W-06
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2. Device Name

a. Proprietary Name: 3M™ Attest™ Rapid Read-Out Biological Indicator (#1292)
b. Device Common/Usual Name: Biological indicator
c. Device Classification Name: Biological Sterilization Process Indicators

3. Identification of Predicate Device:

3M™ Attest™ Rapid Read-Out Biological Indicator (#1292), K926364

4. Device Description:

The 3M™ Attest™ 1292 Rapid Readout Biological Indicator, RRBI, is a dual readout biological indicator system specifically designed for rapid and reliable monitoring of steam sterilization process when used in conjunction with the 3M™ Attest™ 190/290 Auto-readers.

The Attest 1292 RRBI detects the presence of *Geobacillus stearothermophilus*, (formerly known as *Bacillus stearothermophilus*), by detecting the activity of alpha-glucosidase, an enzyme present within the organism. The presence of the enzyme is detected by reading fluorescence produced by the enzymatic breakdown of a non-fluorescent substrate. This creates a fluorescence change, which is detected by the Attest 290 Auto-reader. A fluorescence change indicates a steam sterilization process failure. The Attest 1292 RRBI also detects the presence of *G. stearothermophilus* organisms by a visual color change reaction. Biochemical activity of the *G. stearothermophilus* organism produces acid by-products that cause the media

to change color from purple to yellow. A visual pH color change also indicates a steam sterilization process failure. The 3M™ Attest™ Rapid Read-Out Biological Indicator is identical in design and performance specifications (with exception of the calculation of survival/kill) to the predicate device.

5. Indication For Use:

Use the Attest 1292 RRBI to monitor:
1. 250°F (121°C) gravity steam sterilization cycles.
2. 270°F (132°C) vacuum assisted steam sterilization cycles.

6. Description of Modification

The purpose of this filing is to move from a survival tested at 5 minutes and a kill tested at 15 minutes to a calculated survival/kill testing on a lot-by-lot basis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bryan Becker
Regulatory Affairs Specialist
3M Company
3M Center, Building 275-5W-06
Saint Paul, Minnesota 55133-3275

APR 2 9 2009

Re: K090569
Trade/Device Name: 3M™ Attest™ Rapid Read –Out Biological Indicator (#1292)
Regulation Number: 880.2800
Regulatory Class: II
Product Code: FRC
Dated: April 22, 2009
Received: April 23, 2009

Dear Mr. Becker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Christine D. Walton for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.0 Indications for Use

510(k) Number (if known): K090569

Device Name: 3M™ Attest™ Rapid Read-Out Biological Indicator (#1292)

Indications For Use:

Use the Attest 1292 RRBI to monitor:
1. 250°F (121°C) gravity steam sterilization cycles.
2. 270°F (132°C) vacuum assisted steam sterilization cycles.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090569